

REMARKS

The Examiner provides a number of rejections and we list them here in the order in which they are addressed:

- I. Claims 1-21 are rejected under 35 USC § 103(a)
 - A. Claims 1-3, 10-13 and 17-21 are allegedly unpatentable over United States Patent No. 4,522,786 To Ebersole.
 - B. Claims 1-21 are allegedly unpatentable over United States Patent No. 5,048,554 To Kremer.
- II. Claims 18-21 are rejected under 35 USC § 112
 - A. ¶ 1: as allegedly containing subject matter not described in the specification.
 - B. ¶ 2: as allegedly being indefinite for failing to particularly point out and distinctly claim the invention. Further, Claim 18 is allegedly "unclear" as to how the heating and other steps restrict flow.
- III. The Specification Is Objected To For Failing To Provide Proper Antecedent Basis For The Claimed Subject Matter.
- IV. The Examiner Suggests The Application Is A Continuation-In-Part.
- V. The Examiner Requests Formal Drawings.

I. Claims 1-21 Are Not Obvious

A. Ebersole Does Not Create A *Prima Facie* Case Of Obviousness

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the reference(s) themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. *In re Vaeck*, 947 F.2d 488, 20 USPQ.2d 1438 (Fed. Cir. 1991); and *MPEP* § 2142; Establishing A *Prima Facie* Case Of Obviousness. The Examiner is reminded that if ONLY ONE of the above requirements is not met, then a *prima facie* case of obviousness does not exist. In the present

Office Action, the Applicants clearly demonstrate that the Examiner's rejection does not meet these criterion. The Applicants rebut the establishment of a *prima facie* case of obviousness by the argument below.

The Examiner rejected Claims 1-3, 10-13 and 17-21 under 35 U.S.C. §103(a) as being unpatentable over Ebersole (United States Patent No. 4,522,786). Specifically, the Examiner states "Ebersole teaches a device and method for restricting flow from one layer of a test device to another layer via a barrier layer ... [which] has pores (the instant microchannels) impregnated with a polymer material ... that melts upon application of heat to permit flow through the pores ... ". *Office Action*, ¶ 16. The Examiner admits that "Ebersole fails to explicitly teach a heating element associated with the meltable material in the substrate", but that it "would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a heating element in the constant temperature surface ... ". *Office Action*, ¶ 17 and ¶ 18, respectively. Applicants disagree, and respectfully submit that the Examiner has failed to establish a *prima facie* case of obviousness.

The Examiner is reminded, that under law, an Examiner is not one skilled in the art. Moreover, the MPEP requires that scientific points made by the Examiner be suggested by reference to a document:

"Assertions of technical facts in areas of esoteric technology must always be supported by citation of some reference work." MPEP §2144.03.

The Examiner has pointed to no reference work or evidence to support the assertion that it would be obvious to include a heating element in the constant temperature surface of Ebersole. This is not permitted. As such, the Examiner has failed to teach this claim limitation for all of the rejected claims.

Nonetheless, in order to further the Applicants' business interests and the prosecution of the present application, yet without acquiescing to the Examiner's arguments, and without waiving the right to prosecute the original claims in the future, Applicants have amended Claims 1 and 10¹, while concomitantly canceling Claims 2 and 12 without prejudice, to recite intersecting first and second etched microchannels. Ebersole also fails to teach this claimed embodiment and the Examiner has provided no evidence showing that one skilled in the art

¹ The Applicants now regard Claim 18 as substantially similar to Claim 10. Applicants therefore cancel Claims 18-21 without prejudice.

would necessarily modify Ebersole to provide etched and intersecting microchannels. As such, the cited prior art and the Examiner's argument fail to teach every element, and do not provide any motivation to modify Ebersole.

The Applicants, therefore, respectfully request the Examiner withdraw the rejection and allow Claims 1, 3, 10, 11 and 13 - 17.

B. Kremer Is Non-Analogous Art

The Examiner has rejected Claims 1-21 under 35 U.S.C. §103(a) as being unpatentable over Kremer (United States Patent No. 5,048,554). Specifically, the Examiner states "Kremer teaches a valve [within a cylinder] having a diaphragm 26 in contact with meltable material 32 ..." and "... if the cylinder is exposed to heat that generates excessive pressure, the meltable material melts and the diaphragm is moved by cylinder pressure to pressurize the meltable material which escapes via the elastic o-ring." *Office Action*, ¶ 20.

Applicants submit that Kremer is non-analogous art. Non-analogous art exists when, on a factual basis, a cited reference is not within the field of the inventor's endeavor or is not reasonably pertinent to the particular problem with which the invention was involved. *Finish Engineering Co., Inc. v. Zerpa Industries, Inc.*, 806 F.2d 1041, 1 USPQ2d 1114, 1116 (Fed. Cir. 1986).

Kremer is not within the Applicants' field of endeavor and one skilled in the art of the Applicants' field of endeavor would not be motivated to seek out Kremer. Kremer clearly falls within the field of endeavor related to the safe construction and use of pressurized gas cylinders. This is quite different from the Applicants' field of endeavor related to thermal microvalves controlling microchannel fluid flow.

Kremer is also not reasonably pertinent to the particular problem involved with the Applicants' presently claimed embodiment. Kremer relates to the problem of a pressurized gas cylinder prematurely bursting when at a normal, or near normal, filling pressure;

It has, however, been observed that the diaphragm may also burst when it should not burst, in other words without any elevated pressure or at a slight elevated pressure. This generally occurs when the diaphragms have been in service for a certain period and when they are worn or weakened by repeated stress. *col 1 ln 20-25*.

On the other hand, the Applicants' presently claimed embodiment solves problems related to the movement of fluid samples (*i.e.*, for example, biological samples) in microdroplets through microchannels.

For example;

The present invention relates to microfabrication of microscale devices and reactions in microscale devices, and in particular, movement of biological samples in microdroplets through microchannels to initiate biological reactions. *Applicants' Specification, pg 5 ln 14-16.*

Clearly, Kremer is not pertinent to solving any problems related to fluid flow through microchannels, for any purpose, particularly those relevant to controlling biological reactions. The Applicants, therefore, respectfully request the Examiner to withdraw Kremer as a 35 USC § 103(a) cited reference.

II. Rejections to Claims 18-21 Under 35 USC § 112 Are Moot

The Examiner states that Claims 18-21 are "... not described in the specification in such a way to reasonable convey to one skilled in the relevant art that the inventor(s), at the time the application was filed had possession of the claimed invention..." because "There is no teaching in the specification of heating a meltable material so as to produce anisotropic expansion of the material to induce movement of the material from one channel to another to restrict flow". *Office Action, ¶ 3.* The Applicants point out that this rejection is now moot because Claim 18 was cancelled for other reasons (see above footnote).

Applicants respectfully request the Examiner withdraw all rejections under 35 USC § 112.

III. The Antecedent Basis Objection Is Moot

The Examiner objects to the specification as not having proper antecedent basis for the claimed subject matter. The Applicants disagree, but point out that this rejection is now moot based on the cancellation of Claim 18 for other reasons.

Applicants respectfully request the Examiner withdraw this objection.

IV. The Application Is Properly A Divisional

The Examiner suggests the application "may constitute a continuation-in-part of the prior application" because "this application repeats a substantial portion of ... [the prior application] ... and adds and claims additional disclosure not presented in the prior application." *Office Action*, ¶ 3. The Applicants disagree because the present specification exactly duplicates the originally filed parent specification.

The Examiner is further reminded of the Restriction Requirement contained within the Examiner's Amendment accompanying the Notice Of Allowance in the parent application 08/888,309 (mailed 06/08/99). The '309 Restriction Requirement separated then pending Claims 1-44 into Group I (Claims 1-17: drawn to a heating method and device) and Group II (Claims 18-44: drawn to a method of restricting fluid flow). In the parent application, Claims 18-44 were elected and issued as United States Patent 6,048,734. Concomitantly, Claims 1-17 were withdrawn without prejudice in the parent application and were re-presented in the present divisional application for prosecution.

The Applicants respectfully request the present application, containing the pending Claims 1-17, be made of record as a divisional application to reflect the prosecution of the non-elected Claims (*i.e.*, Group I) of the parent application.

For the convenience of the Examiner, Applicants have provided an amendment to the originally submitted relation statement (see Application Transmittal Sheet Paragraph 14). Also, the Applicants provide an amended paragraph to insert an inadvertently omitted term "not" also corrected by amendment in the parent application.

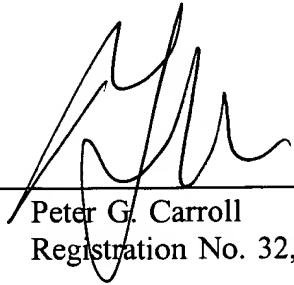
V. Formal Drawings Are Provided

The Examiner states that "This application, filed under former 37 CFR 1.60, lacks formal drawings. *Office Action*, ¶ 1. The Applicants now provide a set of formal drawings that are identical to those provided in the parent application.

CONCLUSION

The Applicants believe that the arguments and claim amendments set forth above traverse the Examiner's rejections and, therefore, request that all grounds for rejection be withdrawn for the reasons set above. Should the Examiner believe that a telephone interview would aid in the prosecution of this application, the Applicants encourage the Examiner to call the undersigned collect at 617.984.0616.

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